K071214

JUL 31 2007

510(k) Summary Information *Premarket Notification, Section 510(k)*	**Genesee Biomedical, Inc.** **APRIL 30, 2007**

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**

   Trade Name: ATS SIMULUS Adjustable Flexible Annuloplasty Ring Model 735 AF

   Common Name(s): Annuloplasty Ring

   Classification Name(s): Ring, Annuloplasty

2. **Establishment Name & Registration Number:**

   Name: **Genesee Biomedical, Inc.**
   Number: 1723241

3. **Classification(s):**

   Device Class: Class II
   Classification Panel: Cardiovascular Devices Panel
   Product Code(s): KRH

4. **Equivalent Predicate Device:**

   Genesee Biomedical Inc's. SIMULUS™ Fully Flexible Annuloplasty Ring Model 700FF (K052565) and Genesee Biomedical Inc's. Sculptor® Adjustable Annuloplasty Ring Model 605M, & Tricuspid Annuloplasty Ring Models 605T (K905175). The device is also equivalent to the Puig Massana-Shiley Annuloplasty Ring (K801876 and K821258).

   Equivalence can be seen in the design, material composition, surgical technique and intended use.

5. **Device Description:**

   The ATS SIMULUS™ Adjustable Flexible Annuloplasty Rings Model 735AF are implantable, adjustable flexible, annular rings (Figure II.1). The rings reduce and stabilize the atrioventricular annulus in patients undergoing mitral or tricuspid valve repair. The body of the ring is made of tubular braided Polyester. The ring contains circumferential flexible radiopaque markers. The entire circumference of the ring is radiopaque.
   The rings are available in the following six sizes: 25 mm, 27 mm, 29 mm, 31 mm, 33 mm and 35 mm. The size refers to the inner circumference of the ring, trigone to trigone.

6. **Packaging:**

The ATS SIMULUS Annuloplasty Rings are supplied STERILE (sterilized by gamma radiation) and non-pyrogenic, packaged in inner and outer Chevron style Tyvek/Polymylar peel pouches. The rings will remain sterile until at least the expiration date provided the package is unopened and undamaged.

7. **Indications for Use:**

The ATS SIMULUS™ Adjustable Flexible Annuloplasty Rings are for use in those patients undergoing surgery of diseased or damaged mitral or tricuspid valves in whom the surgeon determines that the valve can be preserved by employing the appropriate surgical repair. The annuloplasty rings provide support for the mitral or tricuspid annulus and restrict expansion of the annulus

8. **Testing Summary:**

Testing included LAL, Sterility Validation, and Class VI Biocompatibility tests on the predicate device. Mechanical testing was carried out on complete modified rings and ring components. All test results were satisfactory.

9. **Applicant Name & Address:**

John T. M. Wright, Ph.D.
Genesee Biomedical, Inc.
1308 So Jason Street,
Denver, CO 80223
Phone (303) 777-3000 extension 111
Fax (303) 777-8866
Email jwright@geneseebiomedical.com

10. **Registration Number:**

1723241

11. **Company Contact:**

John Wright, Ph.D.
Genesee Biomedical, Inc.

12. **Submission Correspondent:**

John T. M. Wright, Ph D.
Chief Executive Officer
Genesee Biomedical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2007

Genesee BioMedical, Inc.
c/o John T. M. Wright, Ph. D.
Chief Executive Officer
1308 South Jason St.
Denver, CO 80223

Re: K071214
Trade/Device Name: ATS SIMULUS Adjustable Flexible Annuloplasty Ring Model 735AF
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty Ring
Regulatory Class: Class II
Product Code: KRH
Dated: June 28, 2007
Received: June 29, 2007

Dear Dr. Wright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K071214

Device Name(s): **ATS SIMULUS Adjustable Flexible Annuloplasty Ring Model 735AF**

Indications For Use:

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Prescription Use ___X___ OR Over-The-Counter Use _____

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bechtner

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071214

(Per 21 CFR 801.109) (Optional format 1-2-96)